PERRY JOHNSON LABORATORY ACCREDITATION, INC.

Certificate of Accreditation

Perry Johnson Laboratory Accreditation, Inc. has assessed the Laboratory of:

FOCUS Laboratories

894 Marcon Blvd., Suite 150, Allentown, PA 18109

(Hereinafter called the Organization) and hereby declares that Organization is accredited in accordance with the recognized International Standard:

ISO/IEC 17025:2017

This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system
(as outlined by the joint ISO-ILAC-IAF Communiqué dated April 2017):

Chemical, Biological & Biological (Microbiological) Testing

(As detailed in the supplement)

Accreditation claims for such testing and/or calibration services shall only be made from addresses referenced within this certificate. This Accreditation is granted subject to the system rules governing the Accreditation referred to above, and the Organization hereby covenants with the Accreditation body's duty to observe and comply with the said rules.

For PJLA:

Tracy Szerszen
President

Perry Johnson Laboratory Accreditation, Inc. (PJLA)
755 W. Big Beaver, Suite 1325
Troy, Michigan 48084

Initial Accreditation Date:	*Issue Date:*	*Expiration Date:*
August 26, 2014	January 31, 2023	March 31, 2025
Revision Date:	*Accreditation No.:*	*Certificate No.:*
December 18, 2023	77499	L23-77-R2

The validity of this certificate is maintained through ongoing assessments based on a continuous accreditation cycle. The validity of this certificate should be confirmed through the PJLA website: www.pjlabs.com

Certificate of Accreditation: Supplement

FOCUS Laboratories

894 Marcon Blvd., Suite 150, Allentown, PA 18109
Contact Name: Mel Homik Phone: 610-866-7272

Accreditation is granted to the facility to perform the following testing:

FLEX CODE	FIELD OF TEST	ITEMS, MATERIALS, OR PRODUCTS TESTED	COMPONENT, CHARACTERISTIC, PARAMETER TESTED	SPECIFICATION OR STANDARD METHOD	TECHNOLOGY OR TECHNIQUE USED
F1, F4	Chemical [F]	Water and Solutions	USP <643> Total Organic Carbon	FOCUS SOP 2302	Catalytic combustion oxidation
F1, F4			USP <644>, <645> Conductivity	FOCUS SOP 3510	Conductivity Meter
F1, F4	Biological (Microbiological) [F]	Pharmaceutical Products and Materials, Medical Devices, Health and Beauty, and consumer products and material	USP <51> Antimicrobial Effectiveness Testing	FOCUS Protocols 020, 030 / SOP 3470	Plating/Culture
F1, F4			USP <60> Microbiological Examination of Non-sterile Products Tests for Burkholderia cepacia complex	FOCUS SOP 3451	Plating/Culture
F1, F2, F4		Non-Sterile Pharmaceutical Products and Materials, Medical Devices, Health and Beauty Products, Consumer Products, Materials and Toys	USP <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests	FOCUS Protocol 004 / SOP 3410 ASTM F963-17 Section 4.3.6.3	Plating/Culture
F1, F2, F4			USP <62> Microbiological Examination of Nonsterile Products: Tests for specified Microorganism	FOCUS Protocol 005 / SOP 3450 ASTM F963-17 Section 4.3.6.3	Plating/Culture
F1, F4		Water for Pharmaceutical Purposes	Microbial Enumeration and Identification USP <1231>, SMEWW	FOCUS Protocol 001 / SOP 3850	Plating/Culture
F1, F4		Medical Devices, Health and Beauty, and consumer products and materials	ANSI/AAMI/ISO 11737-1 Determination of a Population of Microorganisms (Bioburden)	FOCUS Protocol 014 / SOP 3411	Plating/Culture
F1, F4		Environmental (Air & Surface Sampling)* (*Typically collected in Clean Rooms and Controlled Environments)	USP <797>, USP <1116>, ISO 14698-1 Microbial Enumeration and Identification	FOCUS Protocols 021 / SOP 3431, 010 / SOP 3430, 023 / SOP 3432	Plating, Culture, Biochemcial and Genetic Identification

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F1, F4	Biological [F]	Pharmaceutical Medical Devices, Health, and Beauty Products and Materials	USP <85> Bacterial Endotoxins	FOCUS SOP 3444	Kinetic Turbidimetric or Chromogenic and Gel-Clot

1. The presence of a superscript F means that the laboratory performs testing of the indicated parameter at its fixed location.

2. Typically collected in Clean Rooms and Controlled Environments as outlined in methods.

3. Flex Code:
   F1-Introduction of the testing of a new item, material, matrix, or product for an accredited test method
   F2-Introduction of a new version of an accredited standard method (with no modifications)
   F3-Introduction of a new parameter/component/analyte to an accredited test method
   F4- Introduction of a new version or modifications of an accredited non-standard method
   F5-Introduction of a new method that is equivalent to an accredited method (using same technology or technique)

4. This is the primary site for all quality management system activities.